

AWARD NUMBER: **W81XWH-14-1-0060**

TITLE: **“Preventing Risky Drinking in Veterans Treated w ith Prescription Opioids”**

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REPORT DATE: **April 2017**

TYPE OF REPORT: **Annual**

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE April 2017		2. REPORT TYPE ANNUAL		3. DATES COVERED 1April2016 - 31March2017	
4. TITLE AND SUBTITLE "Preventing Risky Drinking in Veterans Treated with Prescription Opioids"				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-14-1-0060	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) James McKay, Ph.D. E-Mail: jimrache@mail.med.upenn.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Pennsylvania 3451 Walnut Street, P-221 Philadelphia, PA 19104-6205				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Veterans who are taking prescription opioids for chronic pain and are engaging in risky drinking are at heightened risk for drug interactions, including overdose and other negative effects, particularly if they are also using benzodiazepines. In this application, we propose to test an integrated prevention intervention, designed to reduce rates of risky drinking in veterans receiving prescription opioids to treat their chronic pain. This adaptive, patient-centered intervention provides integrated clinical assessment, brief intervention, monitoring, and extended prevention services delivered through a combination of clinical visits, telephone calls, and text messages. We propose to conduct a study in which returning OEF/OIF individuals and other veterans receiving medical care at the Philadelphia VAMC (N=300) who are on daily doses of prescription opioids and screen positive for risky alcohol use will be randomized to receive 12 months of an adaptive integrated prevention intervention (IPI) or to standard care (SC), which consists of a Brief Intervention (BI) with 2 follow-up contacts. Potential participants will be veterans at the Philadelphia VAMC who, based on pharmacy records, are using opioids daily to treat chronic pain. An initial evaluation will identify individuals who also engage in risky alcohol use based on NIAAA-recommended guidelines and meet other inclusion criteria to be enrolled in the study. The evaluation will also identify the use of other medications (e.g., benzodiazepines) that could interact negatively with opioid use. For veterans randomized to the IPI condition, a BI is first provided to reduce alcohol to non-hazardous levels and the effects are monitored for one month. Veterans who reduce alcohol use to non-hazardous levels during this one-month period continue in a monitoring track, consisting of tailored text messages and brief monthly telephone contacts. Veterans who continue to drink at risky levels are instead placed in a track that provides tailored text messages and more frequent telephone calls. In addition to monitoring, these calls provide further prevention/BI services to help the veteran reduce alcohol use to non-hazardous levels. Key components of these services are motivational enhancement and development of more effective ways to cope with stress and other triggers for risky alcohol use. All participants will be followed up at 3, 6, 9, 12 and 18 months after baseline. The primary outcome at each follow-up point will be a dichotomous measure of any risky drinking since the prior follow-up (yes/no). Secondary outcomes will include self-reported frequency of heavy drinking, biological measures of alcohol use, other drug use as determined by urine toxicology tests, opioid overdoses, and ratings of depression and pain. Repeated measures analyses will compare the IPI and SC conditions on primary and secondary outcomes assessed across an 18-month follow-up. Analyses will also test hypothesized moderation and mediation effects.					
15. SUBJECT TERMS Nothing listed					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	16	19b. TELEPHONE NUMBER (include area code)

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1. Introduction

Veterans who are taking prescription opioids for chronic pain and are engaging in risky drinking are at heightened risk for drug interactions, including overdose and other negative effects, particularly if they are also using benzodiazepines. In this application, we propose to test an adaptive prevention intervention, designed to reduce rates of risky drinking in veterans receiving prescription opioids to treat their chronic pain. This adaptive, patient-centered intervention provides clinical assessment, brief intervention, monitoring, and extended prevention services delivered through a combination of clinical visits, telephone calls, and text messages. We will conduct a study in which returning OEF/OIF individuals and other veterans receiving medical care at the Philadelphia VAMC (N=300) who are on daily doses of prescription opioids and screen positive for risky alcohol use will be randomized to receive 12 months of an adaptive prevention intervention (API) or to standard care (SC), which consists of a Brief Intervention (BI) only. For veterans randomized to the API condition, a BI is first provided and the effects are monitored for one month. Veterans who reduce alcohol use to non-hazardous levels during this one-month period continue in a monitoring track, consisting of tailored text messages and brief monthly telephone contacts. Veterans who continue to drink at risky levels are instead placed in a track that provides tailored text messages and more frequent telephone calls. These calls provide monitoring and further prevention/BI services to help the veteran reduce alcohol use to non-hazardous levels. Key components of these services are motivational enhancement and development of more effective ways to cope with stress and other triggers for risky alcohol use. Veterans in the API condition who are initially placed in the monitoring track but whose drinking increases again during the 12 month intervention are transferred to the more intensive prevention track, until their alcohol use has again decreased. API is hypothesized to produce better alcohol and other drug use outcomes than SC over an 18-month follow-up.

2. Key words

veterans, opioid medication, pain treatment, risky drinking, prevention, brief intervention, monitoring, adaptive interventions, benzodiazepines, overdose, follow-up

3. Accomplishments

Major Goals of the Project

The goal of the proposed study is to test an adaptive prevention approach designed for returning OEF/OIF individuals and other veterans who are engaging in risky drinking while being treated with prescription opioids for chronic pain. We propose to conduct a study in which returning OEF/OIF individuals and other veterans receiving medical care at the Philadelphia VAMC (N=300) who are on daily doses of prescription opioids and screen positive for risky alcohol use will be randomized to standard care (SC) or to 12 months of the adaptive prevention intervention (API) described above. The primary outcome at each follow-up point will be a dichotomous measure of alcohol use status (any risky alcohol use since the prior follow-up: yes/no). Secondary outcomes will include self-reported frequency of heavy drinking, biological measures of heavy drinking, urine toxicology tests to assess other drug use, opioid overdoses, depression, and pain.

Objectives and Hypotheses

a. Primary objective: To compare the effectiveness of a 12-month adaptive prevention intervention (API) with standard care (SC) over an 18-month follow-up period, for veterans treated with prescription opioids and who are engaging in risky/hazardous drinking, as defined by NIAAA guidelines (5).

- *Hypothesis 1:* API will produce better outcomes than SC, as indicated by lower rates of risky/hazardous alcohol use across the follow-up period.

b. Secondary objectives: To examine secondary outcome measures, moderator effects, and mediation effects:

- *Hypothesis 1:* API will produce better outcomes than SC on frequency of heavy drinking, biological measures of heavy drinking (i.e., GGT and CDT), urine toxicology tests to assess other drug use, depression, and pain.
- *Hypothesis 2:* Rates of opioid overdoses will be lower in API than in SC
- *Hypothesis 3:* Intervention effects will be greater in higher-risk veterans, including those with higher prescription opioid dosages, co-occurring benzodiazepine use, poor social support, and low readiness for change.
- *Hypothesis 4:* Results favoring API over SC on risky drinking will be mediated by greater readiness for change, self-efficacy, and coping.

Milestone	Base Line Plan Date
Task 1: Prepare the text messaging system for the study, and finalize all manuals for the adaptive prevention intervention (API)	15-Oct-2014
Task 2: Pilot test methods to identify veterans with chronic pain who are receiving daily opioid medication through VANC pharmacy records, and the screening procedures to detect risky alcohol use in these individuals	15-Oct-2014
Task 3: Complete training for the two prevention counselors in API, and identify and begin training a third prevention counselor	15-Oct-2014
Task 4: Begin enrollment of study participants	15-Jan-2015
Task 5: Complete enrollment of study participants	01-May-2017
Task 6: Complete all 18-month follow-ups	15-Oct-2018
Task 7: Complete and submit all main outcome papers	30-Jun-2019

Progress Toward Year 3 Milestones:

The primary milestone for Year 3 was to have virtually completed recruitment by the end of the year (with a few last participants to be recruited in Y4). We have clearly not achieved this milestone. We did continue to recruit, enter participants into the study, deliver the study interventions, and conduct follow-up assessments throughout the year. Notably, veterans who have been randomized to the prevention intervention are participating at a high rate. Most (63%) start out in the active prevention track, because they have not reduced their drinking down to safe levels in the month after receiving a brief intervention. However, virtually all of these individuals eventually do reduce their drinking and are able to transfer to the monitoring only track for the rest of the intervention. Moreover, veterans are staying engaged, regardless of whether they are in the active prevention or monitoring only tracks of the intervention. The mean number of completed telephone prevention sessions among veterans who have been in the prevention condition for more than a month is over 12. This indicates the prevention intervention we are testing is feasible to deliver and veterans are likely to engage in it and sustain their participation. However, these observations are based on small numbers to this point.

Major Activities in Year 3:

- **Recruitment at the Corporal Michael J. Crescenz Medical Center (Formerly the Philadelphia VAMC)**
 - Reviewed 1,100+ electronic medical records to identify potentially eligible Veterans.
 - 15% were eligible for a recruitment letter
 - 55% reported no alcohol use
 - 25% were ineligible based on other exclusion criteria
 - 5% were waiting to have opiates renewed
 - **Mailed 138 letters**
 - The majority of letters went to Veterans who reported some alcohol use on the most recent administration on the AUDIT-C by medical staff within the VA system. As the number of unique (new to our list) Veterans prescribed opiates decreased, we were not able to send as many letters as in Year 2.
 - **Performed 131 phone screens, including going back through the list to re-screen Veterans from previous mailings.**
 - Positive screens (N=30)
 - Enrolled 14 (see below)
 - 7 Canceled, no showed or decided they were no longer interested in participating
 - 4 Requested time to think about the study/talk to doctor first, but are not yet enrolled
 - 4 Wanted to wait to schedule baseline until their next VA appointment was scheduled.
 - 1 Other
 - Screening/enrollment failures (N=101)
 - 40% did not meet criteria for risky drinking
 - 37% not interested in participating in the study
 - 9% reported travel difficulties
 - 7% met criteria for moderate or severe SUD, and were referred to treatment
 - 4% did not have a cell phone capable of receiving text messages
 - 3% not taking daily opioids

- **Enrolled and randomized 14 Veterans (see below for totals for entire grant period)**
 - 11 of 14 Veterans enrolled within Year 2 did so in the last two months of Year 3, after a new re-search tech started doing recruitment calls and we lowered the AUDIT-C threshold for study entry.
 - Active: 14
 - Current Condition
 - Prevention Intervention: 9
 - Standard Care: 5
 - Dropout: 0
- **Recruitment of Veterans at University of Pennsylvania**
 - Screened 29 Veterans
 - Positive Screens: 5
 - Enrolled: 2, see below
 - Cancelled baseline appointment: 2
 - No show to baseline: 1
 - Screening Failures: 24
 - 12 were not taking an opiate prescription for chronic pain
 - 5 met criteria for moderate to severe use disorders
 - 5 did not meet criteria for risky drinking
 - 2 did not have a cell phone capable of receiving text messages
 - Enrolled and randomized 2 Veterans
 - Prevention Intervention: 0
 - Brief Intervention Only: 2
- **Recruitment at Pittsburgh VAMC**
 - Per IRB requirements, recruitment at the Pitt VAMC must go through each Veteran's primary care provider. Thus, after the study team reaches out to a Veteran's PCP, the PCP has to pitch the study to the Veteran and offer a handoff to the study team for screening.
 - Number of PCP's contacted: 53
 - Number of Screenings scheduled: 8
 - Number of Screenings completed: 5
 - Number ineligible: 4
 - Did not meet criteria for risky alcohol use: 3
 - Met criteria for moderate to severe use disorder: 1
 - Number eligible: 1
 - No showed to baseline visit (and their scheduled appointment at the medical center that was on the same day).
- **Submitted four modifications to the Corporal Michael J. Crescenzo Medical Center IRB**
 - Modification approved 07/14/2016: Following the repair of the VA housed servers, the server location for electronic data collection returned to the Crescenzo VA. Further, two staff members no longer working on the study (Rosenbach and Van Horn) were removed from the study staff form.
 - Modification approved 10/10/2016: Adding newly hired and cleared research technician, Margaret Lawlace, to the study staff form.
 - Modification approved 2/24/17: The inclusion criteria was lowered to include Veterans with lower AUDIT-C scores, from a 4 down to a 2. Additionally, we modified our method for compensating participants, from cash to the Greenphire ClinCard system. The recruitment script and pre-screening form were modified to comply with the new inclusion threshold.
 - Modification approved 4/7/17: The protocol was modified to allow for the recruitment of Veterans from the Opioid Treatment Program.
- **Continuing review at the Corporal Michael J. Crescenzo Medical Center submitted on 03/24/2017**
- **Submitted three modifications to the University of Pennsylvania IRB**

- Modification approved 4/6/16: Gained approval for paragraph of text to be used distributed via email list serves for recruitment purposes.
 - Modification approved 7/28/16: Gained approval to recruit via Craigslist.
 - Modification approved 9/21/16: Gained approval to recruit via Facebook ads.
 - Modification approved 01/04/17: Gained approval to lower our inclusion threshold, accepting Veterans with AUDIT-C scores of 2, down from scores of 4. Additionally, gained approval to utilize the Greenphire ClinCard system to compensate participants instead of petty cash.
 - Modification submitted 4/24/17: Submitted modification to obtain approval to run advertisements on a local radio station. Two versions were submitted: 60 and 30 second long ads. Approved 4/28/17.
- **Continuing review at the University Pennsylvania approved on 04/06/16**

Total Recruitment in Grant Period Years 1-3:

- **Recruitment at the Corporal Michael J. Crescenzo Medical Center**
 - **Reviewed 4,100+ electronic medical records to identify potentially eligible Veterans**
 - 24% eligible for letter
 - 53% reported no alcohol use
 - 20% were ineligible on other exclusion criteria
 - 3% we waited to contact (waiting for PCP's approval)
 - **Mailed 1189 letters**
 - Majority of letters went to Veterans who reported some alcohol use on the most recent administration of the AUDIT-C by medical staff within the VA system
 - **Completed 818 Screens**
 - Positive screens (N=84)
 - Enrolled: 35, see below
 - No show to baseline appointment: 22
 - Not interested in study: 16
 - Wanted to wait until later date to schedule: 5
 - Other: 6
 - Screening/enrollment failures (N = 734)
 - 50% did not meet criteria for risky drinking
 - 32% not interested in study
 - 5% travel difficulty
 - 5% no longer receiving opiate prescriptions
 - 3% met DSM-V criteria for moderate to severe use disorder
 - 3% did not have cell phone capable of receiving text messages
 - 2% other
 - Enrolled Veterans 35:
 - Active: 31
 - Prevention Intervention: 17
 - Brief Intervention only: 14
 - Dropout: 3
 - Deceased: 1
- **Recruitment at the University of Pennsylvania**
 - Screened Veterans: 29
 - Positive Screens: 5
 - Enrolled 2
 - Screening Failures: 24
 - Contacted 60+ VFW/American Legion Posts
 - 20+ conversations with post commanders
 - Made in person presentations at two VFW's
- **Recruitment at the Pittsburgh VAMC**

- All recruitment at the Pittsburgh site occurred within Year 3, and thus is the same as listed above. We have not recruited any participants from this site.

- **Total enrollment across all three sites:**

- Enrolled: 37
 - Active: 33
 - Prevention Intervention: 17
 - Brief Intervention Only: 16
 - Dropout: 3
 - Deceased: 1

Opportunities for Training and Professional Development

Nothing to report

Dissemination of Results

Nothing to report

Plans During the Next Reporting Period to Accomplish Goals and Objectives

During the upcoming year, we will continue to: (1) recruit veterans into the study from the Philadelphia VA, the greater Philadelphia metro area, and the Pittsburgh VA; (2) conduct baseline assessments and randomize participants; (3) deliver the brief intervention and prevention intervention conditions; and (4) complete research follow-up interviews. We will also implement two new recruitment strategies, enrolling veterans with pain diagnoses and alcohol use from the opioid substitution program at the Philadelphia VA and running radio ads for the study, which are described in more detail below.

4. Impact

Development of the principal discipline of the project:

Nothing to report

Other disciplines:

Nothing to report

Technology transfer:

Nothing to report

Society beyond science and technology:

Nothing to report

5. Changes/Problems

Changes in approach and reasons for change:

During the past year, we made a number of changes in our approach to increase our recruitment rate. These included opening up a second recruitment site at the Pittsburgh VA and lowering the threshold on the AUDIT-C needed to qualify for the study. In addition, we increased our efforts to recruit veterans from outside of the VA system in Philadelphia by running recruitment ads on Facebook and Craigslist, having doctors at Penn pain clinics discuss the study with their veteran patients, and attempting to establish collaborations with veteran's organizations such as VFWs and American Legion Posts in the area.

Actual or anticipated problems or delays and actions or plans to resolve them:

Despite the efforts described above, recruitment continues to be a significant problem. It should be noted that we have not yet been able to recruit any participants in Pittsburgh. The only strategy change that appears to have increased recruitment was lowering the AUDIT-C threshold. Since that change did not occur until near the end of the Year 3, the impact on our sample size is still rather small, but we are encouraged by the initial results. In addition, the new research technician who started doing recruitment in early 2017, Margaret Lawless, has been more successful in her efforts than the prior research techs who were making initial calls to potentially eligible veterans.

We are about to implement two further changes which we hope will further increase recruitment. The first is to advertise the study on a radio station here in Philadelphia that is popular with veterans. We have submitted the proposed ad to the UPENN IRB, and it was just approved. The second change is to initiate recruitment in the opioid substitution programs at the Philadelphia VA. This modification was approved by the DoD, and was just approved by the Philadelphia VA IRB. We have identified about 70 veterans on opioid substitution treatment who are drinking at sufficient levels to qualify for the study and who have a current pain diagnosis. We will begin to screen them immediately.

During the past year, the VA has continued to reduce the number of new prescriptions for opioid medications to treat pain, and to discontinue opioid medications in veterans who admit to alcohol or other drug use. The veterans who are in our study tell us that they know of many other veterans who take opioids for pain and continue to drink. However, they report that these individuals have no intention of telling anyone connected with the VA about their substance use, out of fear of having their opioid medications discontinued. Therefore, we are confident that the new VA policy has not eliminated alcohol use in those on opioids; rather, it has driven it underground. However, we have not been able to come up with a better way of identifying these veterans, or of persuading them to be in our research study.

We are confident that our recruitment rate will go up in the coming year, as the impact of the new lowered AUDIT-C threshold more fully takes effect, Ms. Lawless continues to do our recruiting, we enroll veterans from the opioid substitution program, and our radio ads get airplay. However, we will still be far behind our recruitment goals, even with an increase in recruitment rates. Given that we are underspent, we will have funds to support a sixth year. With that, we could recruit for two more years, and still get a full year of follow-up on the last participants enrolled. This will not get us up to our original planned sample size, but it should make it possible to achieve a sample size of 100-130 veterans.

Changes that had a significant impact on expenditures:

Nothing to report

Significant changes in use or care of human subjects:

Nothing to report

6. Products

Nothing to report

7. Participants & Other Collaborating Organizations

What individuals have worked on the project?

Name:	James McKay, Ph.D.
Project Role:	PI
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to project:	Dr. McKay is directing this research project, which includes chairing weekly staff meetings, preparing all study reports, supervising staff working on the study, representing the study in discussions with the VA and other organizations, coordinating efforts to address problems that emerge, and presenting information about the study and results in professional meetings and publications.
Funding Support:	

Name:	Martin D. Cheattle, M.D.
Project Role:	Co-Investigator
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to project:	Dr. Cheattle is an expert in the treatment of pain, and he has led efforts

	to recruit participants from pain clinics, provided consultation on issues related to the assessment and management of pain, participated in regular staff meetings, and contributed to the writing of reports.
Funding Support:	

Name:	Brenda Curtis, Ph.D.
Project Role:	Co-Investigator
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to project:	Dr. Curtis has provided expertise in the use of text messaging for behavioral health. She provides ongoing input on the text messaging program we are using in the intervention, led efforts to use Craigslist and Facebook to recruit participants, and attended all staff meetings.
Funding Support:	

Name:	April Howard
Project Role:	Prevention Counselor
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to project:	Ms. Howard has provided the prevention intervention to study participants, attended all staff meetings, contributed to the development of the text messaging and counseling components of the intervention, and completed all required VA trainings and documentation of clinical contacts.
Funding Support:	

Name:	Megan Ann Ivey
Project Role:	Coordinator
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to project:	Ms. Ivey has been the coordinator for the study. She has completed protocol amendments to the VA and Penn IRBs, supervised research technicians, monitored the quality and accuracy of data collected, engaged in problem solving around recruitment issues, and attended all staff meetings.
Funding Support:	

Name:	Henry R. Kranzler, Ph.D.
Project Role:	Co-Investigator
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to project:	Dr. Kranzler has participated in staff meetings, provided expertise on interactions between opioids and other medications, and contributed to discussions regarding ways to increase recruitment
Funding Support:	

Name:	Margaret Lawlace
Project Role:	Research Technician
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	12
Contribution to project:	Ms. Lawlace has screened potential participants, enrolled participants, conducted baseline and follow-up interviews, tracked participant progress over time, provided information to determine which track participants in the active intervention were placed in, generated data for quar-

	terly and yearly reports, and facilitated connections between study participants and counselors.
Funding Support:	

Name:	Kevin Lynch, Ph.D.
Project Role:	Statistician
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to project:	Dr. Lynch has contributed to discussions about research design and statistical analyses, and provided updated power calculations to address reduced sample size.
Funding Support:	

Name:	David Oslin, M.D.
Project Role:	Co-Investigator
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to project:	Dr. Oslin has participated in staff meetings and contributed to discussions regarding ways to increase recruitment. In his role at the VA as the Chief of Behavioral Health, he has facilitated connections with various groups at the VA (e.g., Internal Medicine/Primary Care) to facilitate the successful implementation of the study.
Funding Support:	

Name:	Sarah Rosenbach
Project Role:	Research technician
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	3
Contribution to project:	Ms. Rosenbach has identified and screened potential participants, enrolled participants, conducted baseline and follow-up interviews, tracked participant progress over time, provided information to determine which track participants in the active intervention were placed in, generated data for quarterly and yearly reports, and facilitated connections between study participants and counselors.
Funding Support:	

Name:	Max Robert Stern
Project Role:	Research Coordinator
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	8
Contribution to project:	Mr. Stern has completed amendments to the VA and Penn IRBs, supervised research technicians, monitored the quality and accuracy of data collected, engaged in problem solving around recruitment issues, obtained a list every quarter of veterans on opioid medication and merged that with AUDIT-C alcohol screening data to identify potential participants, completed baseline and follow-up assessments, and attended all staff meetings.
Funding Support:	

Name:	Tyrone Thomas
Project Role:	Prevention Counselor
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to project:	Mr. Thomas has provided the prevention intervention to study partici-

	pants, attended all staff meetings, contributed to the development of the text messaging and counseling components of the intervention, and completed all required VA trainings and documentation of clinical contacts.
Funding Support:	

Name:	Barry Vandegrift
Project Role:	Project Manager
Research Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to project:	Mr. Vandegrift has provided administrative support for the study. He assists in preparing scientific and financial reports and processes purchase orders and payments to subcontractor.
Funding Support:	

Change in active other support of the PD/PI(s) or senior/key personnel since last reporting period:
Nothing to Report.

Other Organizations involved as partners
Nothing to Report.

8. Special Reporting Requirements
Attached – See Quad Chart

9. Appendices
Attached – See Graphs

Preventing risky drinking in veterans treated with prescription opioids

NH130003 and
W81XWH-14-1-0060



PI: James McKay, Ph.D.

Org: University of Pennsylvania

Award Amount: \$3,501,673

Study/Product Aim(s)

- Determine the efficacy of a 12 month integrated prevention intervention (IPI for the reduction of hazardous alcohol use in veterans treated with prescription opiates for pain.
- Examine impact of the intervention on secondary outcomes, including other drug use, depression, pain, and overdose rates
- Test whether effects are greater in certain groups: veterans with higher opiate dosages, co-occurring benzodiazepine use, poor social support, and low readiness to change

Approach

Randomized trial comparing IPI to standard VA care in 300 veterans treated with opiate medications for pain. Alcohol, other drug, depression, and pain outcomes will be examined in six follow-ups over an 18 months period. IPI is an adaptive intervention, in which veterans who do not respond to the initial prevention efforts receive additional prevention services

Insert a picture or graphic here, with a caption, that represents the proposed work

Accomplishments: initiated recruitment; added the Pittsburgh VA as a second site, began enrollment of veterans in Philadelphia area who are not receiving services at the VA, maintained a > 80% follow-up rate, intervention is being delivered with good fidelity to the manual and outcomes in veterans receiving the intervention are good.

Timeline and Cost

Activities	CY	14	15	16	17
Complete protocol, enroll subjects					
Continue enrollment; follow-ups					
Complete enrollment; follow-ups					
Continue follow-ups, conduct initial data analyses					
Estimated Budget (\$K)		\$664	\$684	\$821	\$712

Goals/Milestones (Example)

CY14 Goal – Complete all preparatory work, begin enrollment of Ss

☒ Prepare IRB submission, hire staff, complete prevention manuals

CY15 Goals – Continue Ss enrollment, initiate follow-ups

☐ Enrolled 50% of study sample, maintain an 80% follow-up rate

☐ Achieve good adherence to prevention intervention protocol

CY16 Goal – Complete enrollment, continue follow-ups

☐ Achieve projected sample size, maintain 80% follow-up rate

CY17 Goal – Continue follow-ups and begin data analyses

☐ Maintain 80% follow-up rate, examine within-intervention outcomes

Comments/Challenges/Issues/Concerns

- Recruitment continues to be a major problem, despite opening a second site in Pittsburgh. However, new lower alcohol use criteria implemented at the end of the year has increased recruitment.

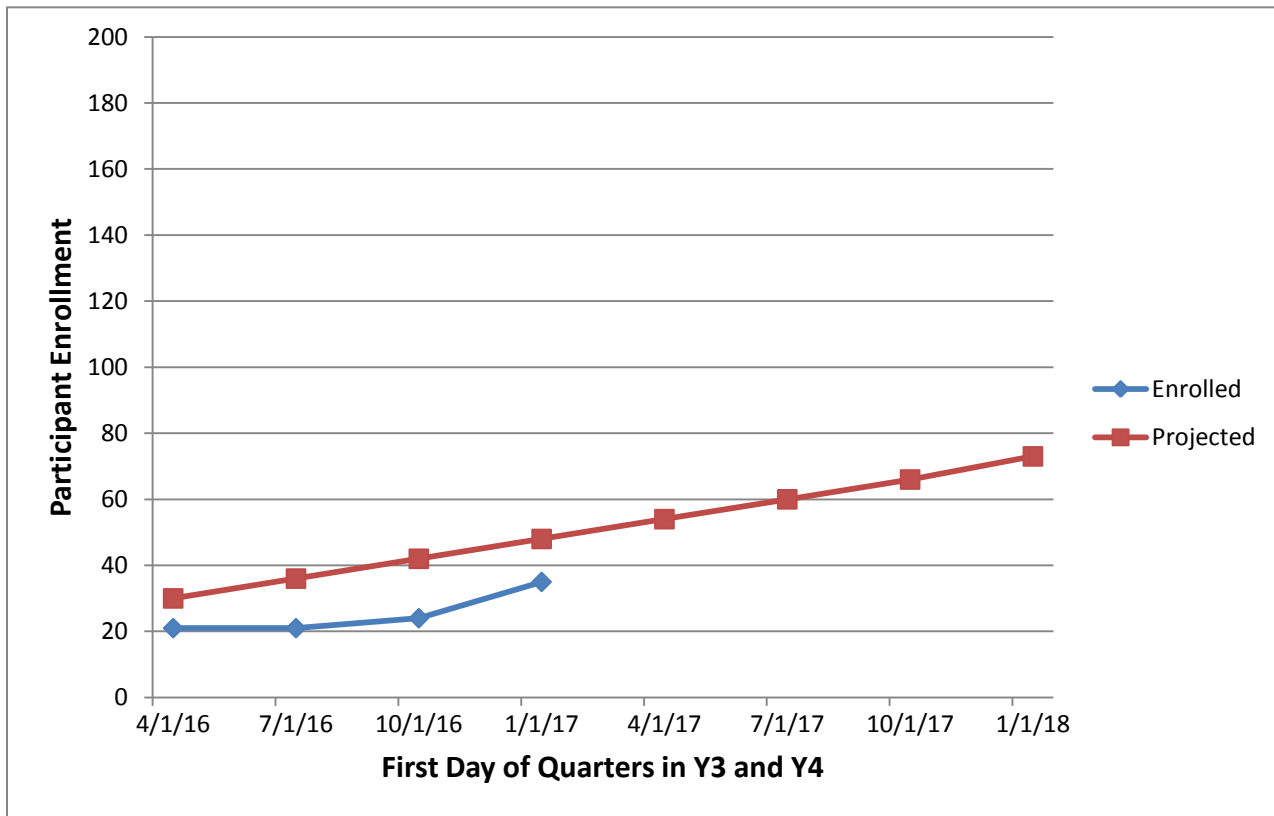
Budget Expenditure to Date

Total Projected Expenditure for duration of award: \$2,018,550.12

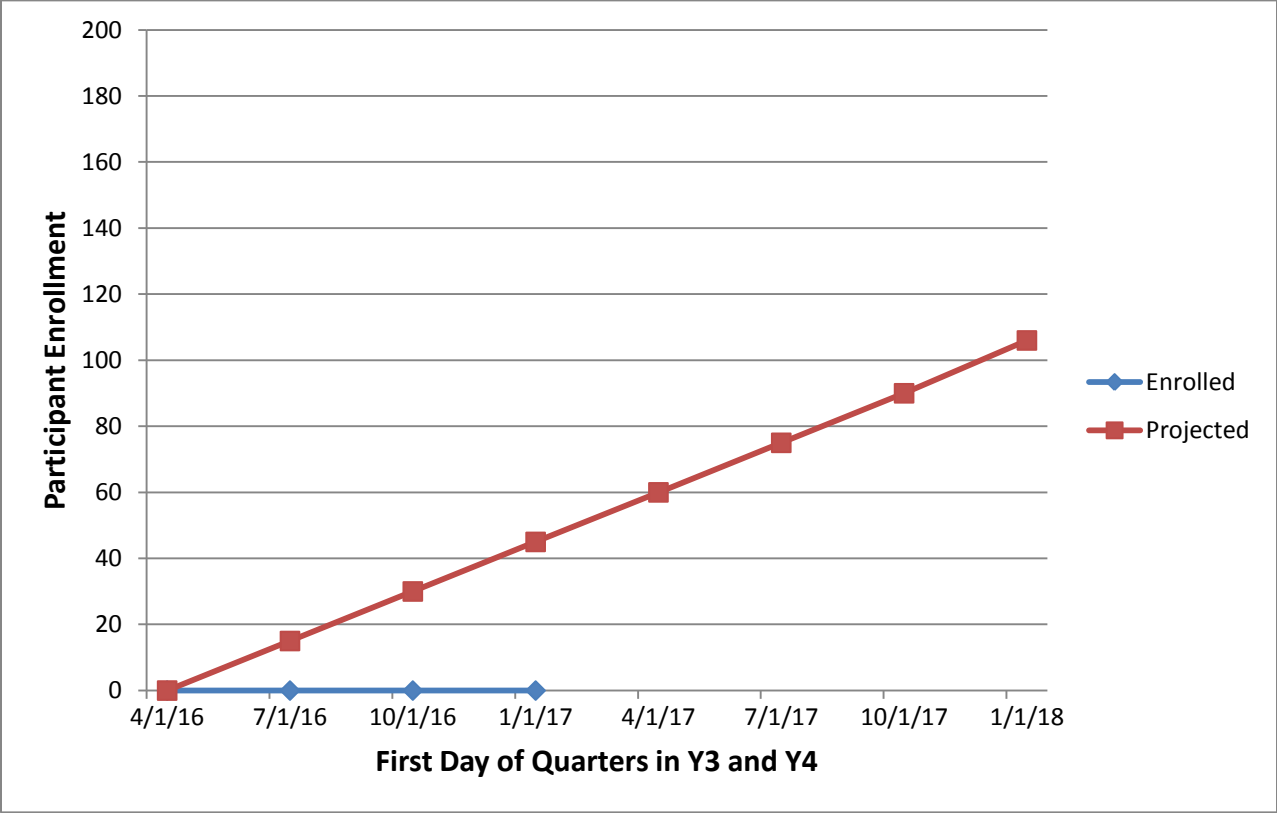
Actual Expenditures for period 04/01/16 – 03/31/17: \$570,364.76

Updated: 04/30/17

Philadelphia VA Site



Pittsburgh VA Site



Penn Site to Recruit Vets Not Getting Treatment at the Philadelphia VA

